

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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NEW YORK STATE RESTAURANT
ASSOCIATION,

No. 07 Civ 5710 (RJH)

Plaintiff,

-against-

NEW YORK CITY BOARD OF HEALTH,
NEW YORK CITY DEPARTMENT OF HEALTH
AND MENTAL HYGIENE, and Thomas R. Frieden,
In His Official Capacity as Commissioner
Of the New York City Department of Health
And Mental Hygiene,

DECLARATION OF
THOMAS R. FRIEDEN

Defendants.

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THOMAS R. FRIEDEN, M.D., M.P.H., hereby declares under penalty of perjury:

1. I am the Commissioner of the Department of Health and Mental Hygiene (the “Department”) of the City of New York and the Chairman of the New York City Board of Health (the “Board”), the defendants in this matter. I have held both of these positions since 2002 and I participated in all aspects of identifying the need for and adopting New York City Health Code §81.50 (“Calorie Labeling”).

2. Pursuant to §556 of the New York City Charter (“Charter”), the Department is charged with regulating all matters affecting health in the City of New York. This responsibility has included, for many decades, supervising and regulating the City’s food service establishments. Charter §556(8). The Department enforces provisions of the New York City Health Code (the “Health Code”), codified in Title 24 of the Rules of the City of New York, and other applicable laws regulating service of food directly to consumers in New York City, including food that is commercially prepared, and sold or distributed for free, in food service establishments (“FSEs”),

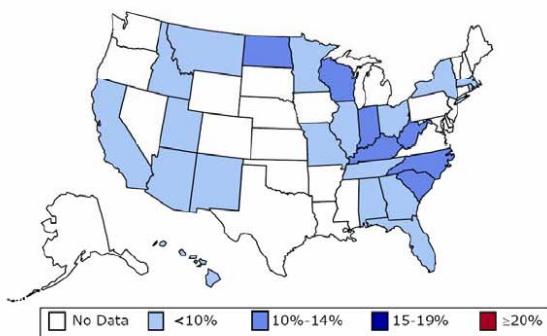
a broad category that includes the restaurants, caterers and mobile food vending units that are important sources of daily food intake in New York City.

3. An obesity epidemic currently undermines the health of many Americans in general and New Yorkers specifically. According to measured height and weight data from the National Health and Nutrition Examination Survey (NHANES), the obesity rate among U.S. adults more than doubled over the past three decades.¹ While 14.5 % of Americans were obese in 1971-1974, the proportion rose to 32.2 % by 2003-2004.²

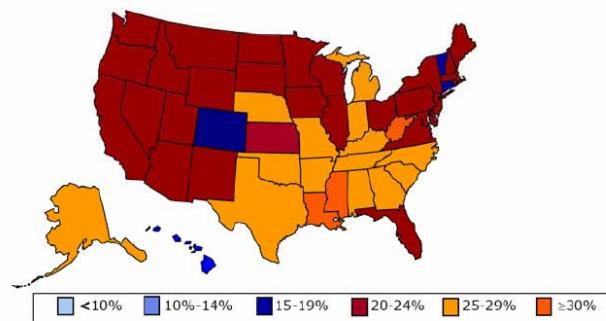
Obesity Trends* Among U.S. Adults

(*BMI ≥ 30 , or ~ 30 lbs overweight for 5'4" woman)

BRFSS, 1986



BRFSS, 2005



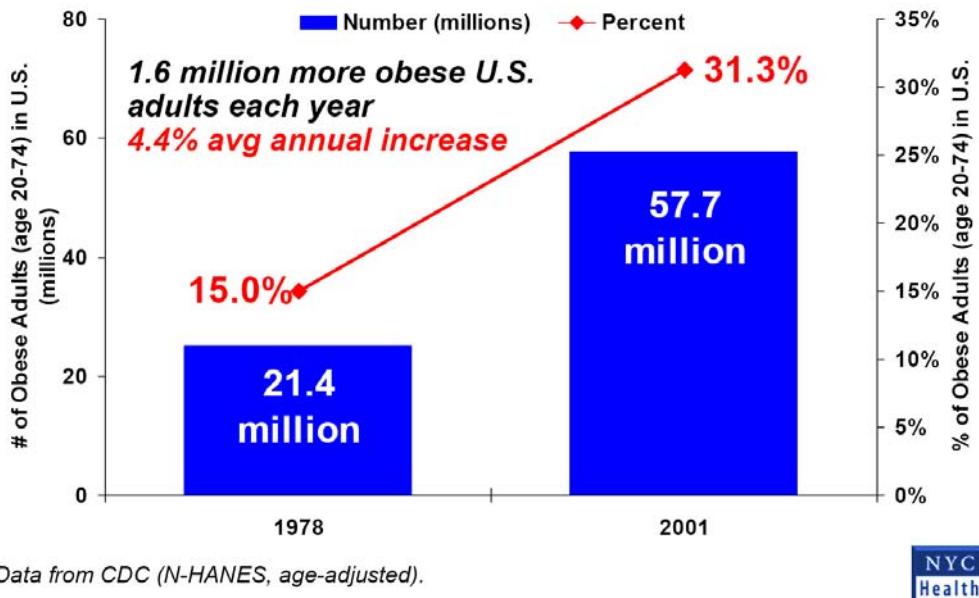
Source: Behavioral Risk Factor Surveillance System, CDC.

¹ Obesity is defined as a body mass index (BMI) of 30 or higher, or about 30 pounds overweight for a 5'4" person. BMI is a number calculated from a person's weight and height (kg / m^2) and is used to screen for weight categories that may lead to health problems.

Source: http://www.cdc.gov/nccdphp/dnpa/bmi/adult_BMI/about_adult_BMI.htm; accessed June 28, 2007.

² Ogden CL, Carroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the United States, 1999-2004. JAMA 2006; 295:1549-1555.

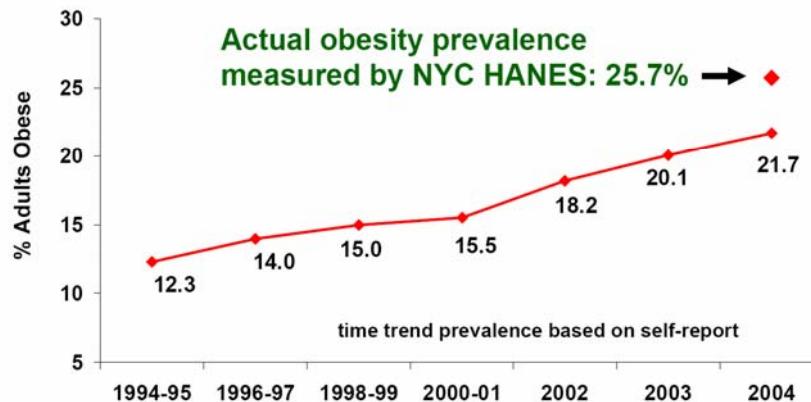
Epidemic of Obesity in the U.S.



In New York City, more than half of adults are overweight (34.4%) or obese (21.7%).³

This rate has been increasing rapidly over the past two decades.

Obesity Prevalence in NYC Increased by More than 70% Obese Adults, NYC, 1994-2004



Sources: Behavioral Risk Factor Surveillance System, Centers for Disease Control and Prevention, 1994-2001; NYC Community Health Survey, New York City Department of Health and Mental Hygiene, 2002-2004; NYC Health and Nutrition Examination Survey, New York City Department of Health and Mental Hygiene, 2004

³ NYC DOHMH. Community Health Survey. Obesity, 2004 (unpublished data)..

4. Studies show that by 1994-1996, an estimated one third of daily caloric intake for all Americans came from foods purchased outside of the home, and that this proportion had nearly doubled in less than 20 years.⁴ Although federally mandated nutrition labeling on food products for sale in supermarkets facilitates informed choice for meals eaten at home, consumers lack such essential information when eating in restaurants. This deficiency is why the Department promoted calorie labeling as one means to address obesity and why the Board of Health, by resolution adopted in September 2006, gave notice of its intention to amend the Health Code to require calorie labeling in New York City FSEs.

5. In December, 2006, after receiving overwhelming support for the proposal in the public comment period, the Board of Health voted unanimously to adopt a Health Code amendment to make already-published calorie information readily apparent in FSEs in a way that would help New Yorkers make more informed choices. The amendment requires that calorie information be made readily apparent to patrons of FSEs at the point of purchase, before they order. With this requirement, New Yorkers will be more likely to make informed choices about the kinds and amounts of food they wish to consume.

6. The Board took this step because the Board and Department are charged with the prevention and control not just of communicable diseases, but also of chronic disease and its risk factors. This charge is addressed by educational and other means that improve the city's environment in ways that will make it easier for New Yorkers to make the healthy choices needed to prevent or manage chronic diseases. Heart disease, stroke, cancer and diabetes—constituted four of the five leading causes of death in New York City in 2005 with 40,771 victims (71.4% of all deaths) – and are all conditions which are significantly more prevalent

⁴ Guthrie JF. et al. Role of Food Prepared Away from Home in the American Diet, 1977-78 Versus 1994-96: Changes and Consequences. *J Nutr Educ Behav* 2002; 34(3):140-150.

among persons who are obese.⁵ The Department noted that obesity, and with it diabetes, are epidemic in New York City. These conditions generate a higher toll of preventable human suffering and use more of society's resources than even the most prevalent communicable diseases at this time.

7. Every era in public health carries its own challenges. I, my colleagues on the Board of Health, and the rest of the Department, take great pride in the historically significant and innovative approaches this Department and the Board of Health have taken to address past public health challenges. In 1896, New York City was the first to require reporting of tuberculosis cases and to establish effective control of that disease. In 1960, eighteen years before the Federal government acted, the Board of Health limited the use of lead-based paint in the interior of this City's residential premises. In 1970, the Board adopted Health Code §173.13, which requires the Department to conduct environmental inspections of homes of lead poisoned children and order the abatement of components covered with lead-based paint. These measures, coupled with the elimination of lead from gasoline have resulted in steady and dramatic declines in the number of lead poisoned children in the City. More recently, in 2006, the Board of Health established stronger requirements for physical activity and nutrition in the City's day care facilities to reduce the prevalence of childhood obesity.

8. With respect to calorie labeling, although consideration was given to requiring that more of the available nutritional information be posted, a choice was made to focus on calorie information because this is, by far, the most important nutrition information for consumers to consider with respect to controlling body weight. Posting already available calorie content information on FSE menus and menu boards will help consumers make more informed choices

⁵ Bureau of Vital Statistics. NYC DOHMH. Summary of Vital Statistics 2005: The City of New York. NYC DOHMH, 2006. Jain A. *What works for obesity? A summary of the research behind obesity intervention.* Minnetonka, MN: BMJ Publishing Group Limited, 2004.

before they select what they eat. The calorie labeling provision is intended to help New Yorkers make more informed choices that can decrease risk for the severe negative health effects of overweight and obesity, which is due primarily to excessive calorie intake. These issues are discussed in greater detail below, as are the specific allegations of the various declarations attached to plaintiffs' complaint.

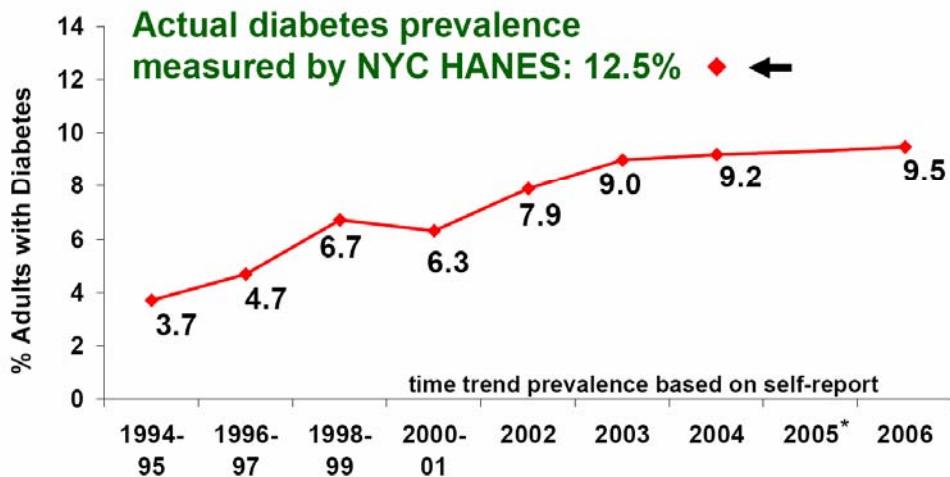
An epidemic of obesity affects New York City adults and children.

9. Obesity, and with it diabetes, are the foremost life-threatening health problems that are growing rapidly worse both in New York City and nationally. People who are overweight are at increased risk for diabetes, heart disease, stroke, high blood pressure, arthritis, and cancer. Diabetes more than doubled over the past decade and now affects 700,000 New Yorkers.⁶ According to the Surgeon General of the United States: "For the vast majority of individuals, overweight and obesity result from excess calorie consumption and/or inadequate physical activity. Unhealthy dietary habits and sedentary behavior together account for approximately 300,000 deaths every year."⁷ Attached hereto as Exhibit 1 is the Surgeon General's Call to Action report.

⁶ Thorpe LE. Mostashari F. Berger DK. Cobb LK. Helgerson SD. Frieden TR. Diabetes is Epidemic. *NYC Vital Signs* NYCDOHMH. 2003;2(1).

⁷ U.S. Department of Health and Human Services. The Surgeon General's call to action to prevent and decrease overweight and obesity. [Rockville, MD]: U.S. Department of Health and Human Services, Public Health Service, Office of the Surgeon General; [2001].

Diabetes Prevalence in NYC More than Doubled in the Past Decade *Adults with Diabetes, NYC, 1994-2006*



*Prevalence not measured in 2005
Sources: Thorpe LE, Mostashari F, Berger DK, Cobb LK, Heigerson SD, Frieden TR. Diabetes is Epidemic. NYC Vital Signs 2003;2(1):1-4 (BRFSS 1994-2001, NYC CHS 2002); NYC Community Health Survey, New York City Department of Health and Mental Hygiene, 2002-2004, 2006; NYC Health and Nutrition Examination Survey, New York City Department of Health and Mental Hygiene, 2004

Obesity causes a wide range of serious health problems

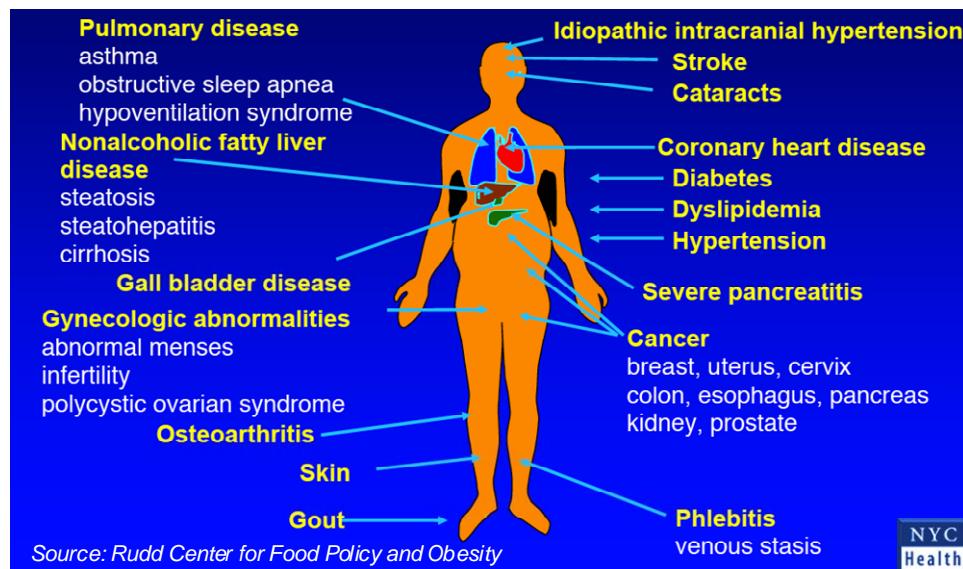
10. Obesity drives the epidemic of type 2 diabetes. Among New Yorkers who have diabetes, 80% are overweight or obese.⁸ People who are overweight or obese are at increased risk for type 2 diabetes, heart disease, stroke, arthritis, gall bladder disease, osteoarthritis, sleep apnea, respiratory problems, depression, and colon, breast, endometrial, and prostate cancers. . . Obesity and overweight in adulthood are associated with large decreases in life expectancy.⁹

⁸ NYC DOHMH Community Health Survey 2006 (unpublished data).

⁹ Peeters A, Barendregt JJ, Willekens F, Mackenbach JP, Al Mamun A, Bonneux L. Overweight and obesity by middle age are associated with a shortened lifespan. Ann Intern Med 2003; 138:24-32.

Medical Complications of Obesity

Almost every organ system is affected



Obesity and diabetes are twin epidemics with devastating health consequences

11. In New York City, diagnosed diabetes prevalence has more than doubled in the past 10 years. More than 9%, or more than half a million (540,000) New Yorkers have diagnosed diabetes, and another 207,000 have it and don't know it.¹⁰ About 23.5%, or 1.3 million, New Yorkers have higher than normal fasting blood sugars that, while not in the range of diabetes, put them at high risk for developing diabetes.¹¹ This condition, known as impaired fasting glucose, is closely linked to overweight and obesity.

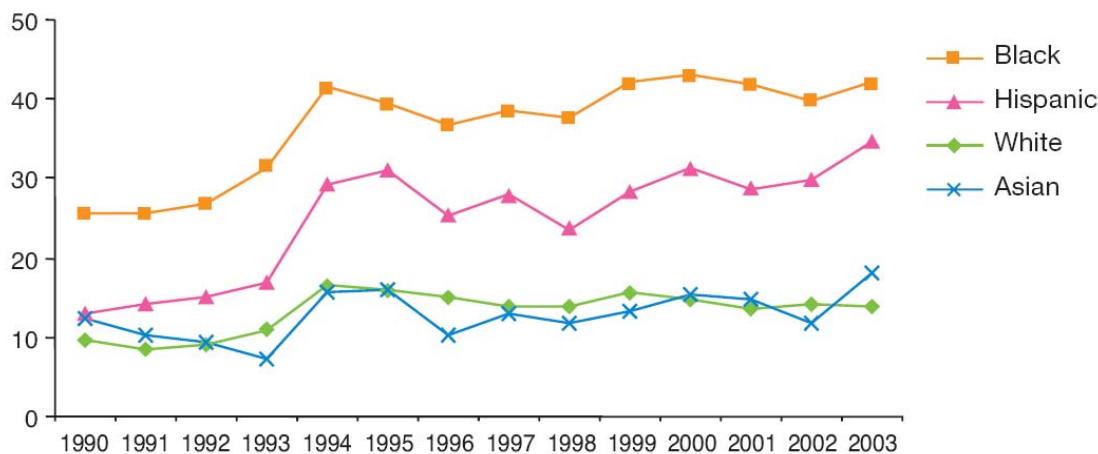
¹⁰ NYC DOHMH Community Health Survey 2006 (unpublished data) and NYC Health and Nutrition Examination Survey 2004.

¹¹ NYCDOHMH, MORE THAN 100,000 NEW YORKERS FACE COMPLICATIONS DUE TO SERIOUSLY OUT-OF-CONTROL DIABETES. Unprecedented Door-to-Door Survey Finds that One Third of New Yorkers with Diabetes Do Not Know they Have the Disease, Press Release, January 30, 2007.

12. Diabetes has devastating complications. In 2003, there were about 22,492¹² hospitalizations and about 1,819 deaths in New York City, with diabetes as the underlying cause of death, making it the fourth leading cause of death, up from sixth in 2002.¹³

Mortality rates from diabetes are increasing in all racial/ethnic groups, though most rapidly in Hispanics

Diabetes mortality rate per 100,000 population, all ages



Rates are age-adjusted to the year 2000 U.S. Standard Population.

Sources: Bureau of Vital Statistics, NYC DOHMH, 1990-2003; U.S. Census 2000/NYC Department of City Planning

Hospitalizations for long-term complications of diabetes have been rising steadily. In 2004, there were 4,865 people on dialysis or receiving kidney transplants in New York City due to diabetes.¹⁴ There were 3,040 lower extremity amputations in 2005 due to diabetes.¹⁵ We estimate

¹² SPARCS hospital discharge data 2003.

¹³ Kim M, Berger D, Matte T. *Diabetes in NYC: Public Health Burden and Disparities*. New York: New York City Department of Health and Mental Hygiene. In press.

¹⁴ Kim M, Berger D, Matte T. *Diabetes in NYC: Public Health Burden and Disparities*. New York: New York City Department of Health and Mental Hygiene. In press.

¹⁵ New York State Department of Health. Statewide Planning and Research Cooperative System. Albany, NY; 2005.

that there are approximately 9,000 New Yorkers blinded by diabetes,¹⁶ and that more than 100,000 New Yorkers with diabetes have had eye damage from diabetes.¹⁷ Attached hereto as Exhibit 2 is the Department's report (in press) "Diabetes in New York City: Public Health Burden and Disparities."

13. This epidemic is also generating extraordinary financial costs to society. A 2002 study by the American Diabetes Association estimates that direct and indirect costs of diabetes were 132 billion dollars.¹⁸ These sums are far larger if other obesity-related disease and lost productivity are taken into account. Health care spending among the obese has been estimated to be 37 percent higher than among those with normal-weight, and increases in the proportion of and spending on obese people relative to people of normal weight accounted for 27 percent of the rise in inflation-adjusted per capita health care spending between 1987 and 2001. These increased costs are borne by families, employers and taxpayers.¹⁹

The nutritional driver of obesity is excess calories.

14. There is agreement among experts that the extraordinarily rapid population-level weight gain that has occurred over the past three decades is a result of the changing environment, rather than biology. The current environment in the U.S. encourages over-consumption of calories, for example, through increasingly large portions of foods and beverages that are energy-dense, easily available, and inexpensive.²⁰ While increasing weight results from an imbalance

¹⁶ M El-Hashimy, MD, K Alich, MS. Blindness caused by diabetes--Massachusetts, 1987-1994. [MMWR Morb Mortal Wkly Rep](#). 1996 Nov 1;45(43):937-41

¹⁷ NYCHANES 2004, unpublished data.

¹⁸ American Diabetes Assn., "Economic Costs of Diabetes in the U.S. in 2002." *Diabetes Care*, v.26, n.3. March 2003.

¹⁹ [Thorpe KE, Florence CS, Howard DH, Joski P](#). The impact of obesity on rising medical spending. [Health Aff \(Millwood\)](#). 2004 Jul-Dec;Suppl Web Exclusives:W4-480-6.

²⁰ Hill JO, Wyatt HR, Reed GW, Peters JC. Obesity and the environment: where do we go from here? *Science* 2003; 299(5608):853-5.

between calories consumed (nutrition) and energy expended (physical activity), it is clear that “rising obesity is primarily the result of consuming more calories.”²¹

15. Studies have documented patterns of increasing portion sizes since the 1970s in a pattern that parallels the epidemic of obesity.^{22,23} On average, portion sizes and energy intake increased for soft drinks by 49 calories, for French fries by 68 calories, and for hamburgers by 97 calories per serving.²⁴ Even small changes, e.g., eating just 10 more calories per day over the course of a year, can result in weight gain of one pound; the potential impact of increases in portion size ranging from 50 to 100 calories is even more dramatic. The public requires better education about the energy content of foods and beverages being consumed. Provision of calorie information on menu and menu boards for each portion size is an important way to accomplish this goal. Attached hereto as Exhibit 3 is the report by Nielsen and Popkin, “Patterns and trends in food portion sizes, 1977-1998, published in JAMA.

16. Americans also increasingly are eating meals away from home. In 1970, Americans spent 26% of their food dollars on foods prepared outside their homes while by 2006 they spent almost half (48%) of their food dollars eating out.²⁵ In 1994-1996, the average American consumed about one third of calories from foods prepared outside of the home, up from 18% less than 20 years earlier.²⁶ Restaurant meals tend to be more calorie-packed than home-cooked

²¹ Bleich S, Cutler D, Murray C, Adams A. Why is the developed world obese? NBER Working Paper # 12954;2007. <http://www.nber.org/papers/w12954>

²² Nielsen, S. J., and B. M. Popkin. Patterns and trends in food portion sizes, 1977-1998. *JAMA* 2003; 289(4):450-453.

²³ Young, L. R. and M. Nestle. The Contribution of Expanding Portion Sizes to the US Obesity Epidemic. *American Journal of Public Health* 2002; 92(2):246-249.

²⁴ Nielsen, S. J., and B. M. Popkin. Patterns and trends in food portion sizes, 1977-1998. *JAMA* 2003; 289(4):450-453.

²⁵ National Restaurant Association (NRA). “Industry at a Glance.” 2005.

²⁶ Guthrie JF. et al. Role of Food Prepared Away from Home in the American Diet, 1977-78 Versus 1994-96: Changes and Consequences. *Society for Nutrition Education* 2002; 34:140-150.

meals, and children eat almost twice as many calories when they eat out than when they eat at home.²⁷

Consumers are interested in calorie information, use it to change their choices, and the public provision of this information is likely to lead to producers making healthier options available.

17. Since 1994, the federal Nutrition Labeling and Education Act (NLEA) has made nutrition information available to consumers on packaged foods purchased in retail stores. This information is widely used. Three-quarters of American adults report using food labels,²⁸ and about half (48%) report that nutrition information on food labels has caused them to change their food purchasing habits.²⁹ The calorie section is both the most prominent, and the most frequently consulted part of the Nutrition Facts panel on packaged foods, with 73% of consumers reporting that they look at calorie information on the Nutrition Facts Panel.³⁰

18. We anticipate that in addition to informing consumers, calorie labeling will motivate the food service industry to improve its menu offerings, in the same way that the packaged food industry reduced trans fat levels in anticipation of the FDA's trans fat labeling rule, which went into effect in 2006.³¹ Attached hereto as Exhibit 4 is the letter from the Grocery Manufacturers of

²⁷ Zoumas-Morse C. et al. Children's Patterns of Macronutrient Intake and Associations with Restaurant and Home Eating" Journal of the American Dietetic Association 2001. 101:923-925.

²⁸ US Department of Health and Human Services (US DHHS), Centers for Disease Control and Prevention, National Center for Health Statistics. *Healthy People 2000 Final Review*. 2001.

²⁹ Levy AS. Derby BM. The Impact of NLEA on Consumers: Recent Findings from FDA's Food Label and Nutrition Tracking System. Washington DC: Center for Food Safety and Applied Nutrition. Food and Drug Administration. 1996.

³⁰ International Food Information Council (IFIC) Foundation. Food & Health Survey: Consumer Attitudes Toward Food, Nutrition & Health. Washington, DC: 2007.

³¹ Grocery Manufacturer's of America. Comments on FDA Advance Notice of Proposed Rule Making Docket No. 2003M-0076. Food Labelling: Trans Fat Acids in Nutrition Labeling. June 18, 2004.

America to the FDA. Some companies have already begun to reduce portion sizes or calorie content of offerings.³²

Calorie imbalance is key and calorie information is by far the single most important piece of nutritional information.

19. Calories are increasingly recognized as the single most important element of nutrition information to address the obesity epidemic. The Food and Drug Administration's Obesity Working Group ("OWG") concluded its 2005 work with a report entitled "Calories Count"³³ whose executive summary stated:

"The OWG's recommendations are centered on the scientific fact that weight control is primarily a function of balance of the calories eaten and calories expended on physical and metabolic activity The recommendations contained in this report therefore focus on a "calories count" emphasis for FDA actions....

OWG Principal Recommended Action Items....

- Calories: Issue an advance notice of proposed rulemaking (ANPRM) to solicit public comment on how to give more prominence to calories on the food label. As examples, increasing the font size for calories, including a percent Daily Value (%DV) column for total calories, and eliminating the listing for calories from fat.

.....

³² TGIJs Initiates Portion Control. <http://food.netscape.com/story/2007/03/09/tgi-fridays-initiates-portion-control/>, accessed July 3, 2007.

³³ U.S. Food and Drug Administration (FDA) and Center for Food Safety and Applied Nutrition (CFSAN). *Calories Count: Report of the Working Group on Obesity*, 2004. <http://www.cfsan.fda.gov/~dms/owg-toc.html> (accessed June 28, 2007).

...Urge the restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for consumers."

Attached hereto as Exhibit 5 is the FDA and Center for Food Safety and Applied Nutrition report, "Calories Count."

20. While calories are just one component of nutritional choice, they are a critically important component. Unburned calories are stored as fat, regardless of whether the calories come from fats, carbohydrates or proteins. Studies of dietary intake in the United States have found that people are eating more calories and more salt, in contrast to other aspects of dietary intake which have improved.³⁴ Average calorie intake for Americans over age 2 increased by nearly 200 calories per day, from 1,791 to 1,983 calories, between 1977 and 1996. Restaurants and fast food were the fastest growing source of calories in this period.³⁵ Attached hereto as Exhibit 6 is the study by Nielsen, Siega-Riz, Popkin, "Trends in energy intake in the United States between 1977-1996."

21. The absence of readily apparent information about calories at the point-of-purchase reduces the ability of consumers to make informed food choices, increasing the likelihood of inadvertent consumption of more calories than expected. This is exacerbated by the increasing frequency with which meals are consumed away from home and steadily increasing portion sizes.^{36,37,38,39,40} With increasing portion sizes, consumers increasingly underestimate calorie

³⁴ Lee S, Harnack L, Jacobs DR, Steffen LM, Arnett DK. Trends in diet quality for coronary heart disease prevention between 1980-82 and 2000-2002: The Minnesota Heart Survey. J Am Diet Assoc. 2007 Feb; 107(2): 213-22.

³⁵ Nielsen SJ, Siega-Riz AM, Popkin BM. Trends in energy intake in the United States between 1977-1996: Similar shifts seen across all age groups. Obesity Res 10:370-378 (2002)

³⁶ Nielsen, S. J., and B. M. Popkin. Patterns and trends in food portion sizes, 1977-1998. JAMA 2003; 289(4):450-453.

³⁷ Young, L. R. and M. Nestle. The Contribution of Expanding Portion Sizes to the US Obesity Epidemic. American Journal of Public Health 2002; 92(2):246-249.

content.^{41,42} Calorie labeling sheds light on differences in the range of choices available. Calorie labeling clarifies the often dramatic differences between ordering, for example, a small portion of McDonalds fries at 250 calories versus a large portion at 570, or their Deluxe Breakfast with syrup at 1,410 calories instead of the Big Breakfast with a regular sized biscuit at 720 calories. It can clarify an even simpler exchange: a large Coke at 310 calories versus a small one for 150 calories or a diet Coke for <1 calories. Add a large beverage (250-350 calories) to the Deluxe Breakfast and an average woman would have already consumed virtually all of her recommended daily intake, and an average man would have consumed 80% of his recommended daily intake.⁴³ The calorie difference with increasing portion sizes is not intuitive from the price differential. An 11% price differential can be accompanied by a 50% differential in calories. For example, going from a McDonald's \$1.79 medium fries with 380 calories to a \$1.99 large fries with 570 calories is an 11% price increase but a 50% calorie increase. Taking a healthy-sounding Starbuck's Green Tea Frappuccino from it's small \$3.75 version to the 32% more expensive large version results in a 76% increase to 650 calories.

22. Although the FDA requires nutrition information to be listed on the Nutrition Facts panels of the labels of packaged foods, this is not the case for foods prepared away from the home. Since neither federal nor state laws require restaurants to post information about calories (or nutrients), consumers have inadequate or no access to information to support healthy choices

³⁸ Guthrie, J. F., B. H. Lin, and E. Frazao. Role of food prepared away from home in the American diet, 1977-78 versus 1994-96: Changes and consequences. *Journal of Nutrition Education and Behavior* 2002; 34(3):140-150.

³⁹ Ello-Martin, J. A., J. H. Ledikwe, and B. J. Rolls. The Influence of Food Portion Size and Energy Density on Energy Intake: Implications for Weight Management. *The American Journal of Clinical Nutrition* 2005; 82(1 Suppl.):236S-241S.

⁴⁰ Young L.R. and Nestle M. Portion Sizes and Obesity: Responses of Fast-Food Companies. *Journal of Public Health Policy* 2007; 28: 238–248.

⁴¹ Young, L. R. and Nestle M.. Expanding Portion Sizes in the U.S. Marketplace: Implications for Nutrition Counseling. *Journal of the American Dietetic Association* 2003; 103(2):231-234.

⁴² Wansink, B. and P. Chandon. Meal Size, Not Body Size, Explains Errors in Estimating the Calorie Content of Meals. *Ann Intern Med.* 2006; 145(5):326-332.

⁴³ U.S. Department of Health and Human Services and U.S. Department of Agriculture. *Dietary Guidelines for Americans*, 2005. 6th Edition, Washington, DC: U.S. Government Printing Office, January 2005.

of foods that comprise one third of their daily calorie intake. This information gap constitutes a significant barrier to healthy food choices.⁴⁴ The Institute of Medicine found that the reach and effectiveness of existing efforts by the FDA and industry fell far short of what they could and should be to provide children, youth and their parents with the information they need using standards and graphics that are easily understood.⁴⁵

The public is able to interpret and use calorie data

23. Calorie content is the metric for energy intake and caloric intake is the most important element of weight control. Weight gain results from more energy consumed (as measured in calories) than expended through physical activity. While there are many other dietary variables of importance to consumers (e.g., fat, sodium), the basic relationship of calories to energy balance and weight control is fundamental.⁴⁶ Calorie content is appropriately the highest priority focus of regulations to require nutrition information in food service. Even if consumers are unaware of their daily recommended calorie intake, they can, by comparing calorie levels of different menu items, make more informed decisions. Even modest reductions in calorie intake can dramatically improve health. A reduction of 300 calories twice per week (the difference between a large diet and sugar-sweetened soda) could result in a weight loss of more than 8 pounds in a year. This is equivalent to the weight loss documented in a landmark study which found that progression to diabetes from pre-diabetes was reduced 58% in people who received a

⁴⁴ U.S. Food and Drug Administration (FDA) and Center for Food Safety and Applied Nutrition (CFSAN). *Counting Calories: Report of the Working Group on Obesity*,” 2004. <http://www.cfsan.fda.gov/~dms/owg-toc.html> (accessed June 28, 2007).

⁴⁵ Institute of Medicine. *Food Marketing to Children and Youth: Threat or Opportunity*. National Academies Press: Washington, DC, 2006.

⁴⁶ U.S. Food and Drug Administration (FDA) and Center for Food Safety and Applied Nutrition (CFSAN). *Counting Calories: Report of the Working Group on Obesity*,” 2004. <http://www.cfsan.fda.gov/~dms/owg-toc.html> (accessed June 28, 2007).

lifestyle support program and underwent moderate weight loss and modest increases in physical activity.⁴⁷ If the 1.3 million New Yorkers with pre-diabetes were to achieve the same level of these modest changes, at least 188,000 cases of diabetes would be prevented over the next three years, avoiding the resultant burden of heart disease, blindness, kidney failure, and amputations. Calorie labeling can help consumers reduce calorie intake.

24. The differences in calories are not always intuitively obvious, and a far lower calorie option is often available within a group of similar products. For example, calories in cheeseburgers at Burger King vary more than three-fold, not even counting the fries and drinks:

Cheeseburger	330 calories
Whopper Junior with cheese:	410 calories
Double Whopper with cheese	990 calories
Triple Whopper with cheese	1230 calories

A consumer ordering a salad at Burger King with the goal of eating food with fewer calories might be startled to learn that dressing can have more calories than the salad and the calories can vary two-fold from 300 to 670 – not counting the croutons:

BK Tendergrill Chicken Garden Salad	240 calories
BK Tendercrisp Chicken Garden salad	400 calories
Ken's Fat free Ranch Dressing	60 calories
Kens' Honey Mustard Dressing	270 calories

Haugen Dec. Ex. A

Or if choosing a dessert at McDonald's, calories can vary more than ten-fold

McDonald's shakes	420-1160 calories
McDonald's hot fudge sundae	330 calories
Fruit and yogurt parfait with granola	160 calories
Vanilla low fat ice cream cone	150 calories
Apple dippers w/ low fat caramel dip	105 calories

⁴⁷ Diabetes Prevention Program Research Group. Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin. J Med. 2002; 346: 393-403.

DeMuth Dec. Ex. D

Both common sense and published scientific evidence indicate that making this information readily available at the point of purchase will influence some consumers to make lower calorie choices.⁴⁸ Attached hereto as Exhibit 7 is Burton, et al, "Attacking the Obesity Epidemic: The Potential Health Benefits of Providing Nutrition Information in Restaurants."

25. The final report of the FDA-commissioned Keystone Forum on Away-From-Home Foods recommends that food service establishments "... provide consumers with calorie information in a standard format that is easily accessible and easy to use ... when standing at a counter, while reviewing a menu board, in a car when reading a drive-through menu, or when sitting down at a table reviewing a menu."⁴⁹ Putting calorie information next to menu items is consistent with this recommendation. This was the first recommendation of the report's Chapter 3, "Increasing the Availability of Low-Calorie Products, Menu Items, and Meals" and was conspicuously absent from the complaint, which cited only the Chapter's second recommendation. Attached hereto as Exhibit 8 is the Executive Summary and Chapter 3 of the Keystone Forum report.

26. Consumers would be best informed by calorie information that is easily accessible at the point of purchase. A recent study found that when calorie information is readily available, high-calorie menu items are chosen one-third less often.⁵⁰ National polls indicate that at least

⁴⁸ Burton S, Creyer EH, Kees J, Huggins K. Attacking the obesity epidemic: the potential health benefits of providing nutrition information in restaurants. Am J Public Health. 2006; 96:1669-1675.

⁴⁹ The Keystone Center. The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity. Final Report. May 2006. Washington, D.C. [Report commissioned by the U.S. Food and Drug Administration.] URL: http://www.keystone.org/spp/documents/Forum_Report_FINAL_5-30-06.pdf.

⁵⁰ Burton S, Creyer EH, Kees J, et al. Attacking the obesity epidemic: the potential health benefits of providing nutrition information in restaurants. Am J Public Health. 2006; 96:1669-1675.

60% of respondents would like calories to be listed on menus or menu boards in chain restaurants.^{51,52}

27. With increasing portion sizes, relative calorie counts that can be compared across menu items become even more important. The larger a meal people eat, the less they think they eat as a percentage of total calories.⁵³

28. Listing calories for restaurant items is a strategy to increase awareness of energy intake. However, contrary to claims in the complaint, establishments are in no way limited by regulations in Health Code §81.50 from providing additional nutrient information (such as sodium, saturated fat or carbohydrates) to complement the provision of calories. Section 81.50 simply establishes a minimum requirement. Establishments that wish to provide additional information are free to do so.

Nine out of Ten Consumers Do Not See Currently Furnished Information.

29. Current nutrition information practices of the FSEs that would be covered under Health Code §81.50 do not effectively transmit information about calorie content to consumers, contrary to the claims in the declarations and complaint. The Department conducted a large exit interview survey of 11,865 diners at a random sample of 274 of the FSEs affected by this rule in May and June of this year. We found that less than 8% of customers report seeing calorie information in the FSE. The percentage was particularly low (< 5%) among those FSEs

⁵¹ The Keystone Center. The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity. Final Report. May 2006. Washington, D.C. [Report commissioned by the U.S. Food and Drug Administration.] URL: http://www.keystone.org/spp/documents/Forum_Report_FINAL_5-30-06.pdf.

⁵² Malone C and Bland-Campbell J. (ARAMARK), New Insights on the Away-From-Home Eating Patterns and Nutritional Preferences of Americans, presentation at the North American Association for the Study of Obesity Annual Scientific Meeting, October 17, 2005. (Results of an online nationwide survey of 5,279 adults.). www.aramark.com/CaseStudyWhitePaperDetail.aspx?PostingID=420&ChannelID=221.

⁵³ Wansink, B. and P. Chandon. Meal Size, Not Body Size, Explains Errors in Estimating the Calorie Content of Meals. Ann Intern Med. 2006; 145(5):326-332.

(McDonald's, Dunkin' Donuts, Burger King, and Yum Brands locations) who have submitted declarations in support of plaintiffs' complaint and whose declarations claim that they provide extensive nutrition information to customers. See, Table 1, below. The numerous McDonald's initiatives described in the DeMuth Declaration at ¶¶ 4-13 are completely invisible to the overwhelming majority of consumers who stand on line each day and choose items from McDonald's menu boards. We believe that these numbers are low because the information is generally provided in ways that are very difficult for consumers to find. At most restaurants, people can only guess the nutrient content of foods at the point of purchase. These current voluntary attempts by some food service establishments to make available nutrition information are inadequate particularly because the information is usually not displayed where and when consumers are making their choices and purchases. When FSEs' nutrition information is available on the internet, patrons need to have access to off-site websites. Such information may also be available in brochures, on placemats covered with food items, or on food wrappers, where the information is hard to find or difficult to read and only accessible after the purchase is made. Thus the information as provided has little or no impact on choice.⁵⁴

30. Interestingly, only at Subway, which, at the time of the survey, was already placing some nutritional information on a sticker posted on the glass display cases near the cash register, was there a substantial rate of consumers reporting that they see calorie information (31% of customers). With labeling provided as required by Health Code §81.50 in the future, consumers will be even more likely to see the information needed for informed choice.

Subway subsequently posted its calorie information in compliance with Health Code §81.50, demonstrating the feasibility of implementing this rule.

⁵⁴ Support for Nutrition Labeling in Fast Food and Other Chain Restaurants. *American Journal of Public Health*. Policy Statements. November 9, 2004. P. 28-29. URL: <http://www.apha.org/legislative/policy/2004/2004-14.pdf>

Table 1. Percent of consumers who see calorie information at New York City establishments covered under Health Code §81.50 (“Calorie Labeling”), with their existing information practices in May-June 2007

Brand	# of Sites	# of Customers Interviewed	% of Customers who Reported Seeing Calorie Information in the Restaurant
Dominos	10	57	0.0%
Papa Johns	5	222	0.0%
Popeyes	7	512	0.6%
Dunkin Donuts	70	2756	1.3%
Starbucks	37	1285	2.7%
Au Bon Pain	2	166	3.7%
Burger King	20	1033	3.8%
Yum Brand	21	861	4.6%
McDonald's	45	2593	4.7%
Wendy's	11	474	6.9%
Subway	48	1906	31.3%

31. Marketing research has shown that providing nutrition information affects consumer attitudes and purchasing intentions. Consumers consistently underestimate the nutrient levels in food items and overestimate the healthfulness of restaurant items.⁵⁵ When consumers are made aware of nutrition information at the point of purchase, disease risk perceptions increase, attitudes toward the product change, and purchasing intentions for unhealthy products decrease.^{56,57} Presenting nutrition information on restaurant menus empowers consumers and can improve food choices.⁵⁸

32. Without calorie information, it is difficult for consumers to compare options and make informed decisions. Recent studies found that 9 out of 10 people underestimated the calorie content of less-healthy items, and that they did so by an average of more than 600 calories

⁵⁵ Burton S. Creyer EH. What consumers don't know *can* hurt them: Consumer evaluations and disease risk perceptions of restaurant menu items. *The Journal of Consumer Affairs*. 2004; 38(1):121-145.

⁵⁶ Burton S. Creyer EH. What consumers don't know *can* hurt them: Consumer evaluations and disease risk perceptions of restaurant menu items. *The Journal of Consumer Affairs*. 2004; 38(1):121-145.

⁵⁷ Kozup JC. Creyer EH. Burton S. Making Healthful Food Choices: The Influence of Health Claims and Nutrition Information on Consumers' Evaluations of Packaged Food Products and Restaurant Menu Items. *Journal of Marketing*. 2003; 67:19-34.

⁵⁸ Burton S. Creyer EH. What consumers don't know *can* hurt them: Consumer evaluations and disease risk perceptions of restaurant menu items. *The Journal of Consumer Affairs*. 2004; 38(1):121-145.

(almost 50% less than the actual calorie content).⁵⁹ When calorie information was provided, consumers chose high-calorie items 24% to 37% less often. Even experienced nutrition professionals have difficulty accurately estimating the calorie content of restaurant food. In one study, while these professionals could accurately describe the calories in a cup of milk, they generally under-estimated calories in restaurant food by 200 to 600 calories. For example, dietitians estimated on average that a typical dinner hamburger with onion rings meal had 865 calories when it actually had 1,550. If not even experienced professionals in the field of nutrition are able to accurately estimate the calorie content of restaurant foods, consumers are even more unlikely to understand caloric content.⁶⁰ Although FSEs provide nutritional information publicly, they fail to provide that information in a way that is useful to consumers. In the current state of information and marketing, consumers consistently underestimate calories in high calorie quick service restaurant foods. Current information practices of the establishments do little or nothing to correct these misperceptions as evidenced by Table 1. The public is suffering because of these misperceptions.

33. Provision of calorie information in restaurants can have an impact even if not all patrons make use of the information. Assuming that half of consumers make use of restaurant nutrition information (as suggested by Krukowski, et al.⁶¹), calorie labeling would have a substantial public health impact. If diners consume 600 more calories than they believe they would consume in one restaurant meal per week, this is 30,000 extra calories a year, or an inadvertent weight gain of up to 9 pounds. National estimates suggest that affecting energy

⁵⁹ Burton S. Creyer EH. et al. Attacking the obesity epidemic: the potential health benefits of providing nutrition information in restaurants. *Am J Public Health*. 2006; 96(9):1669-1675.

⁶⁰ J. Backstrand, et al., *Fat Chance* (Washington, DC: Center for Science in the Public Interest, 1997).

⁶¹ Krukowski RA, Harvey-Berino J, Kolodinsky J, Narsana RT, Desisto TP. Consumers may not use or understand calorie labeling in restaurants. *J Am Diet Assoc* 2006; 106(6):917-20.

balance by roughly this same amount (100 calories per day, or 10 pounds per year) could alter the trajectory of the average weight gain that is driving the obesity epidemic.⁶²

34. Studies consistently show that consumers strongly and increasingly favor having easy access to this information. Six nationally representative polls have found that between 62% to 87% of Americans support requiring restaurants to list nutrition information.^{63,64}

35. The Department's regulation requires that calorie information be provided for any menu items whose content and portion size are standardized and for which calorie content information is made publicly available. Information is to be provided for the standard menu item as usually offered for sale (i.e., the base product, in the portion size as offered for sale). Alternatively, FSEs may present the range of calories under certain conditions.

**Few FSEs opted out of providing calorie information,
and the impact of their decision is very limited.**

36. While we regret that a small number of FSEs declined to continue to make nutritional information publicly available after March 1, 2007, this decision affected less than 6% of the sites that would have been regulated based on December 2006 availability of information. Since the number of consumers actually seeing information is so low today (see Table 1), we believe that this small but unfortunate and correctable loss will be far more than compensated by the increased visibility of information at most sites.

⁶² Hill JO, Wyatt HR, Reed GW, Peters JC. Obesity and the environment: where do we go from here? *Science* 2003; 299(5608):853-5.

⁶³ Center for Science in the Public Interest. Anyone's Guess: The need for nutrition labeling at fast-food and other chain restaurants. Washington, DC: Center for Science in the Public Interest, 2003.

⁶⁴ Harvard Forums on Health. Obesity as a Public Health Issue: A Look at Solutions. National Poll by Lake, Snell, Perry & Associates. June 2003.

37. Plaintiff's declarations fail to mention that the regulation does not prevent any FSE from providing any additional nutrition information voluntarily. Statements that the regulation in any way restricts the provision of additional information are inaccurate.

**Calorie labeling is just one of many approaches
to address growing overweight and obesity**

38. The rapid increase in rates of overweight and obesity in the United States over the past several decades has occurred too rapidly for changes in genetics to be an important cause. The emerging obesity epidemic is due to changes in the food environment and physical activity levels, resulting in more calories consumed than used.⁶⁵ Many social, behavioral, environmental, economic and biologic factors affect obesity and chronic disease, and the Department does not propose that calorie labeling alone can reverse this epidemic. It is one of a series of policy efforts being pursued to improve education and empower consumers by providing tools to support healthier choices. A recent edition of the Department's Health Bulletin series, "How to Lose Weight And Keep It Off" is just one publication that exemplifies the Department's educational approach for consumers.⁶⁶ Another is a recent issue of the Department's City Health Information series that assists health care providers in "Preventing and Managing Overweight and Obesity in Adults."⁶⁷ Attached hereto as Exhibit 9 are copies of these and another publication, "How Many Calories Do People Need Each Day?"

39. There is a broad range of measures being undertaken by the Department and the City to help New Yorkers prevent or reverse weight gain. There have been extensive educational

⁶⁵ U.S. Food and Drug Administration (FDA) and Center for Food Safety and Applied Nutrition (CFSAN). *Counting Calories, Report of the Working Group on Obesity*, Introduction and Appendix B "Text Boxes on Body Mass Index (BMI), Energy (Calorie) Balance, Carbohydrates and Other Macronutrient Contributions to Caloric Value," 2004. <http://www.cfsan.fda.gov/~dms/owg-appb.html> (accessed June 18, 2007).

⁶⁶ NYC DOHMH. *How to lose weight and keep it off*. Health Bulletin (#51) 2007; 6(5).

⁶⁷ Berger DK, Lee KK, Silver LD. Preventing and Managing Overweight and Obesity in Adults. *City Health Information*. April/May 2007;26(4):23-30.

messages; new Health Code regulations for day care services that mandate minimum daily requirements of physical activities for very young children and improved nutritional standards; extensive training and equipping of staff of children's institutions in physical activity; promoting programs for physical activity in schools and for adults; creation of bicycle paths; improvements in school food and creation of the New York City Food Policy Task Force.

**Intent of regulation is to improve public health
by providing information at the point of sale.**

40. The challenged regulation is not intended to put any FSE in a non-competitive position with respect to any other FSE. The only intent is to improve the public's health and reduce obesity by giving the affected FSE's patrons the ability to make their choices at the point of sale, and not when it is too late to make a different choice. In fact, it is entirely plausible that consumers, who are increasingly choosing foods based on nutritional value or perceptions of healthfulness, will prefer purchasing at restaurants where calorie information is available. Posting calorie information on menu boards makes calorie information clear and not confusing, as some declarants have written. See, e.g., declaration of Rick Colon. Posting calorie content on the menu board will facilitate informed individual choice between higher and lower calorie options, and will communicate the information more readily and immediately to customers, rather than hiding it in small type in a densely printed brochure or poster. No new words are being put into the mouths of the plaintiff that aren't already there, in other, less accessible, formats.

41. The current regulation was never intended to, and does not burden any FSE by requiring an FSE that didn't already make information publicly available - such as in brochures, signage, websites, or other means - to analyze its menu from scratch. The only requirement is that the posted calorie content information be calculated in accordance with the FDA's rules, 21

CFR §101.9(c)(1)(i) or a successor regulation, and be prominently displayed at the point of choice and purchase, so the choice can be made before the purchase.

42. The argument that requiring posting by some and not all FSEs will create a competitive disadvantage for those FSEs is purely speculative, as is the allegation that these FSEs will lose business. Again, an equally speculative argument could be raised that it would increase business in these FSEs. Similar dire predictions were raised when New York City amended the Smoke-Free Air Act (“SFAA”), effective in March, 2003, to eliminate all tobacco smoking from virtually all indoor workplaces, including all FSEs, restaurants and bars. The City’s limitations on public smoking, coupled with other measures, have reduced the numbers and percentages of people who currently smoke in the City, which has decreased by 240,000 people (19%), preventing 80,000 premature deaths from smoking.⁶⁸

43. Furthermore, dire predictions made about the effects of smoke-free legislation on business failed to materialize. From April 1, 2003 through January 31, 2004, business tax receipts in restaurants and bars increased 8.7%; from March to December 2003, and employment in restaurants and bars increased by 10,600 jobs (about 2,800 seasonally adjusted jobs).⁶⁹

44. Similar to predictions around the smoke-free air act, we predict that these dire predictions will prove baseless. The proposal to require calorie labeling had widespread social support during an active public comment period. It is equally likely that the availability of calorie information to consumers may come to be seen as a competitive advantage by plaintiff and its patrons.

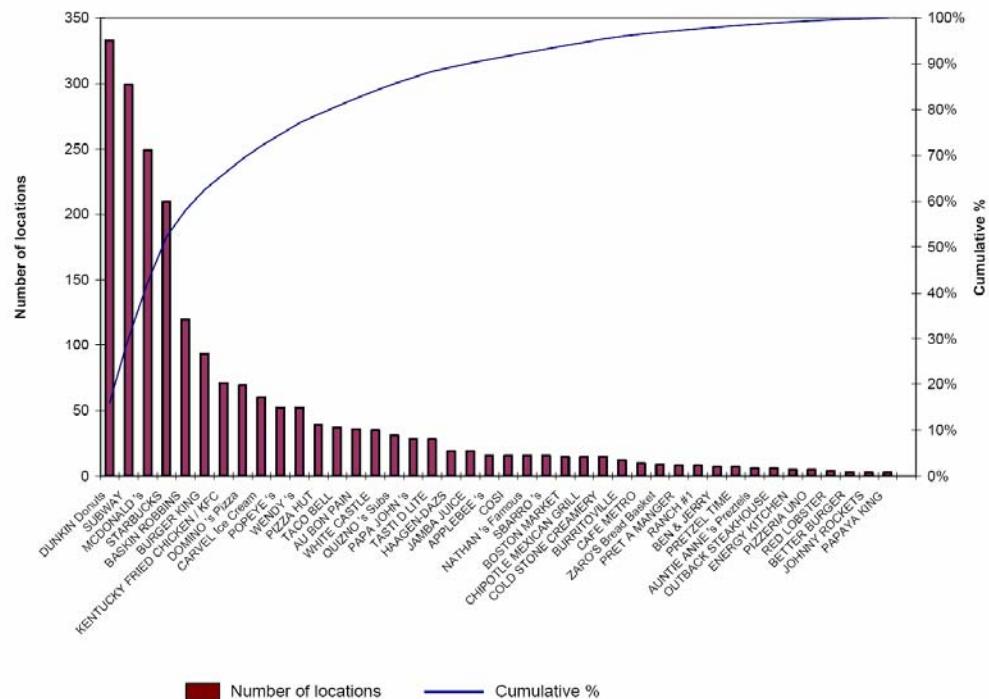
⁶⁸ Decline in Smoking Prevalence in new York City 2002-2006. Morbidity and Mortality Weekly Reports. June 22, 2007 / Vol. 56 / No. 24

⁶⁹ NYC Department of Finance, NYC Department of Health & Mental Hygiene, NYC Department of Small Business Services, NYC Economic Development Corporation. The state of smoke-free New York City: A one-year review. 2004.

Fast Food Consumption is Associated with High Calorie Intake and Overweight

45. Nearly all (>90%) of the food service establishments required to post calorie information on menus and menu boards are quick service or “fast food establishments.”

Distribution of Number of Locations by FSE Chain making Calorie Information Available on March 1, 2007



While eating out, diners typically consume about one third more calories than are eaten at home. A number of studies suggest that specifically regarding fast food patrons, those who often frequent fast food establishments consume more calories than those who frequent fast food establishments less often or not at all and that eating fast food is directly associated with obesity

and overweight in both children and adults.⁷⁰ A large national cohort study showed that adolescent girls whose fast food consumption was classified as “high” ate 130 calories more per day than those who ate fast food less often.⁷¹ This same association has been found among Mexican children in San Diego, where 4-7-year-old children were twice as likely to be obese if they ate in fast food restaurants,⁷² among African American adults in North Carolina, where report of “usual or often” eating in fast food restaurants was associated with obesity,⁷³ and among Minnesota secondary school students.⁷⁴

46. Follow up studies further strengthen the causal nature of the association between eating fast food, high calorie intake and weight gain, and the important differences between fast food and other types of restaurant food. The Coronary Artery Risk Development in Young Adults Study, which tracked young adults over time, showed that 40% of participants increased away-from-home food consumption. The authors noted, “Cross-sectionally, fast food, but not restaurant food, consumption was positively associated with BMI [body mass index]”; high

⁷⁰ Guthrie JF. et al. Role of Food Prepared Away from Home in the American Diet, 1977-78 Versus 1994-96: Changes and Consequences. *J Nutr Educ Behav* 2002; 34(3):140-150.

⁷¹ Schmidt M, Affenito SG, Striegel-Moore R, Khoury PR, Barton B, Crawford P, Kronsberg S, Schreiber G, Obarzanek E, Daniels S. Fast-food intake and diet quality in black and white girls: the National Heart, Lung, and Blood Institute Growth and Health Study. *Archives of Pediatrics & Adolescent Medicine*. 159(7):626-31, 2005.

⁷² Duerksen, SC, Elder JP, Arredondo E, et al. Family restaurant choices are associated with child and adult overweight status in Mexican-American families. *Journal of the American Dietetic Association* 2007;107(5):849-53.

⁷³ Satia JA. Galanko JA. Siega-Riz AM. Eating at fast-food restaurants is associated with dietary intake, demographic, psychosocial and behavioural factors among African Americans in North Carolina. *Public Health Nutrition*. 7(8):1089-96, 2004 Dec.

⁷⁴ French SA. Story M. Neumark-Sztainer D. Fulkerson JA. Hannan P. Fast food restaurant use among adolescents: associations with nutrient intake, food choices and behavioral and psychosocial variables. *International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity*. 25(12):1823-33, 2001 Dec.

consumption of fast food was associated with higher rates of being overweight.⁷⁵ Data from 17,370 adults and children who participated in the 1994-1996 and 1998 Continuing Survey of Food Intakes by Individuals showed that adults and children who reported eating fast food had higher energy intake,⁷⁶ a conclusion also reached in the Pound of Prevention study of nearly 900 women, where follow up at 3 years showed frequency of eating at fast food restaurants was associated with higher total energy intake.⁷⁷

Targeting Children: Fast food marketing

47. An additional reason why the provision of accurate calorie information to consumers by these FSEs is especially justified is that unlike many other FSEs, many of the regulated establishments make extensive use of advertising to promote their products, particularly to vulnerable groups such as children. The major chains use marketing strategies directly aimed at children to establish a preference for their fast food brand,⁷⁸ and children who view such television advertisements are about 50% more likely to eat fast food.⁷⁹ Such advertising does not contain any information about caloric content or the risk of obesity in those patronizing fast food regularly, and many such advertisements may inaccurately imply that fast food is healthy food.

⁷⁵ Duffey KJ, Gordon-Larsen P, Jacobs DR, Williams OD, Popkin BM. Differential associations of fast food and restaurant food consumption with 3-y change in body mass index: the Coronary Artery Risk Development in Young Adults Study. American Journal of Clinical Nutrition. 85(1):201-8, 2007 Jan.

⁷⁶ Paeratakul S, Ferdinand DP, Champagne CM, Ryan DH, Bray GA. Fast-food consumption among US adults and children: dietary and nutrient intake profile. Journal of the American Dietetic Association. 103(10):1332-8, 2003 Oct

⁷⁷ French SA, Harnack L, Jeffery RW. Fast food restaurant use among women in the Pound of Prevention study: dietary, behavioral and demographic correlates. International Journal of Obesity & Related Metabolic Disorders: Journal of the International Association for the Study of Obesity. 24(10):1353-9, 2000 Oct.

⁷⁸ Connor SM. Food-related advertising on preschool television: building brand recognition in young viewers. Pediatrics. 118(4):1478-85, 2006

⁷⁹ Taveras EM, Sandora TJ, Shih M-C, Ross-Degnan D, Goldmann DA, Gillman M W. The association of television and video viewing with fast food intake by preschool-age children. Obesity. 14(11):2034-41, 2006 Nov

Given the epidemic of childhood obesity, calorie labeling may also be an important tool to help parents offset the effects of advertising on children who lack sufficient discernment to evaluate the content of advertising.

48. Children are not the only vulnerable groups who are more likely to eat fast foods. Its nutritional content makes fast food a “good buy” using the metric of cost per calorie. This contributes to the observation that fast food is consumed disproportionately by the poor.⁸⁰

Calorie labeling at these FSEs will make a difference.

49. The Department issues permits to more than 23,000 FSEs. Of these, an estimated 2,375 FSEs, or 10%, have made calorie information publicly available for standardized menu items and are required by Health Code §81.50 to post calorie information on their menus and menu boards. Although New York City-specific data are not available, 2004 national estimates suggest that about one-fifth of main meals and snacks are purchased away from home, amounting to more than 200 meals per person.⁸¹ Supposing that that the 2,375 affected restaurants served only 10% of restaurant meals, in proportion to their share of the total number of food service establishments, this would be the equivalent of about 20-25 meals per person per year. Since even modest calorie reductions will have a major impact on the trajectory of the obesity epidemic, if calorie labeling led to choices that reduced calorie intake by just 150-200 calories for each of these 20 meals, this would lead to a weight loss of one pound per person in a year. Thus, providing calorie information for “just” 10 percent of restaurant meals has substantial

⁸⁰ Drenowski A, Specter SE. Poverty and obesity . The role of energy density and energy costs. Am J Clin Nutr 2004;79:6-16.

⁸¹ The NPD Group, presentation to the Keystone Forum on Away-from-Home Foods, April 26, 2005.

potential for public health impact. A one pound weight loss for every person would help avert the continued upward trajectory of weight gain that New York City witnessed in recent years.

50. But there is good reason to assume that by regulating 2,375 restaurants which made calorie information publicly available as of March 1 2007 there will be a health impact that far exceeds that which is predicted based on these estimates. Restaurants that have made publicly available calorie information are almost all quick service chains, settings that use standardized food preparation. And even in the unlikely event the calorie labeling regulation had little or no impact on consumer food choices, it is likely to increase the number of lower-calorie, and reduce the number of higher-calorie offerings these facilities provide. And even if the regulation neither changed consumer choices nor FSE offerings, there would be a salutary effect on increasing consumer awareness of calorie content.

Major Restaurant Chains' Market Share in NYC

51. Data suggest quick service restaurants account for the bulk of customer traffic in restaurants (i.e., far more than 10% of meals). Nationally in 2004, these establishments accounted for nearly three-quarters of all customer traffic.⁸² Further, restaurant chains, both major (51%) and small (13%) accounted for nearly two-thirds of all restaurant traffic.⁸³ National time trend data suggest that independent restaurants have a declining share of customer traffic. In other words, there is every reason to assume that the 10% of restaurants affected by §81.50 serve a much larger share of meals than reflected in their numbers.

52. The specific major chain restaurants affected by these regulations account for a disproportionately large share of total restaurant visits, on the order of 40% nationwide. This

⁸² The NPD Group, presentation to the Keystone Forum on Away-from-Home Foods, April 26, 2005.

⁸³ The NPD Group, presentation to the Keystone Forum on Away-from-Home Foods, April 26, 2005.

estimate does not include a significant group of restaurants that are subject to these regulations but are not classified as major chains (according to industry definitions), and which further increases any estimate of the impact of these regulations.⁸⁴

53. Furthermore, even if these restaurants accounted for “just” 10 percent of visits, taking into consideration New York City’s \$9.5 billion annual restaurant revenue and average meal check size in New York City (conservatively estimated at \$9.08), more than 100 million meals, and possibly as many as 400 million, would be affected by this regulation each year. This means calorie labeling provides at least 100 million and possibly more than 400 million opportunities a year to positively affect New Yorkers’ eating habits.⁸⁵

The scientific community and the public overwhelmingly support calorie labeling

54. Public interest at the time of the proposal was substantial, and more than 2,200 comments were received. These comments were 100:1 in favor. Of the approximately 2,200 written and oral comments received, all but 22 supported the amendment. National, state and local organizations that submitted statements supporting the proposal included:

- American Medical Association
- American Diabetes Association
- American Cancer Society
- Center for Science in the Public Interest
- National Hispanic Medical Association
- New York Academy of Medicine
- Institute for Urban Family Health
- Medical Society of the State of New York

⁸⁴ NPD Group, 2005 (as cited by Ducey, Erica. “Major chains post biggest market share increases in 2005.” Nation’s Restaurant News 19 December 2005. Accessed 29 June 2007 at:

http://findarticles.com/p/articles/mi_m3190/is_51_39/ai_n15967678),⁸⁴ NPD’s definition of “Major Restaurant Chains” was applied to restaurants identified on Restaurants & Institutions’ Top 400 Chain Restaurants rankings. (Hume, Scott. “The Power Elite.” Restaurants & Institutions 1 July 2006. Accessed 29 June 2007 at: <http://www.rimag.com/archives/2006/07a/top400/top-400.asp>).

⁸⁵ DOHMH calculated this value by adjusting the value of the 2004 national average check size of \$6.06 (calculated by the NPD Group in 2005) for inflation (up to \$6.67 using the CPI) and the cost of living in New York City (up to \$9.08 using the ACCRA Cost of Living Index).

- Northern Manhattan Perinatal Partnership
- Citizen's Committee for Children
- Conscious Cooking
- FoodChange
- New York Coalition for Healthy School Lunches
- American Medical Student Association (local)
- Harlem Consumer Education Council
- Empire State Medical Association (New York State Affiliate of the National Medical Association)
- American Society of Hypertension - Eastern Regional Chapter
- American College of Cardiology (NYS chapter)
- New York Cardiologic Society
- Public Health Association of New York City (PHANYC)
- Baum Forum
- East Harlem Partnership for Diabetes Health and Prevention
- Community Health Care Association of New York State (CHCANYS)
- Community Service Society of New York
- Campaign for Bronx Health
- Citizens Advice Bureau
- Family Cook Production
- For a Better Bronx
- Health People
- Urban Health Plan.

Supportive statements were received from the following universities, medical schools and local hospitals:

- New York University Department of Nutrition, Food Studies, and Public Health
- New York University Nutrition and Dietetics Program
- New York University School of Medicine
- Columbia University Mailman School of Public Health
- Columbia University Medical Center
- Columbia University – New York Presbyterian
- Harlem Hospital Center
- Linking Food in the Environment (LIFE, Columbia University – Teacher's College)
- North General Hospital
- Montefiore Medical Center
- Jacobi Medical Center Family Weight Management Program
- Chapters 2 and 3 of the New York State Academy of Pediatrics
- Mount Sinai School of Medicine
- Tufts University – Friedman School of Nutrition Science and Policy
- Yale University – Rudd Center for Food Policy and Obesity

Attached hereto as Exhibit 11 are representative comments received by the Board of Health in support of Health Code §81.50 from the American Academy of Pediatrics; American Cancer Society-Eastern Division; American College of Cardiology-New York State Chapter; American Medical Association; Citizens' Committee for Children; Community Service Society; and New York University Department of Nutrition, Food Studies and Public Health.

**While the original requirement is quite feasible,
DOHMH has been flexible regarding the “at least as prominent” standard.**

55. The final regulation was amended in response to industry comments to enable FSEs to exercise flexibility in how they display calorie information at the point of purchase, subject to the Department's prior approval and to meeting the “equal prominence” standard specified in the regulation. Unfortunately, most of the alternative proposals failed to even remotely come close to the standard of “equal prominence”. At the same time, several chains, such as Arby's and Auntie Anne's submitted good faith designs to comply with the rules. Subway and Johnny Rocket's have put the new menus and boards into place without alternative designs. Their work demonstrates clearly that, acting in good faith, labeling can be provided while still offering clear, attractive and uncluttered menu boards.

Subway Menu Boards in Place in Manhattan on July 2, 2007



Auntie Anne's Menu Board

Pretzels	2.49
Original 370 cals	Cinnamon Sugar 450 cals
Almond 400 cals	Glazin' Raisin® 510 cals
Garlic 350 cals	Sour Cream & Onion 340 cals
Jalapeño 310 cals	Whole Wheat 370 cals
Sesame 410 cals	
Pretzel Stix 370 cals	2.99

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Summary of DOHMH criteria and allowable alternatives.

56. Health Code §81.50 (b) provides that “Subject to prior approval by the Department, food service establishments may use alternative means for making calorie information available to patrons, provided such information is made available at the point of purchase and is at least as prominent as required in paragraph (1) below.” Subparagraph A of paragraph (1) specifies that on menu boards “calorie content values shall be posted in a size and typeface at least as large as the name of the menu item or price, whichever is larger.” Attached hereto as Exhibit 10 is the Notice of Adoption of an Amendment (§81.50) to Article 81 of the New York City Health Code.

57. This language was added to the regulation after the Department received comments from and met with several restaurant groups, in order to allow for alternative calorie labeling designs. The Department recognizes that these corporations have design expertise that potentially could be deployed to communicate calorie information as effectively as otherwise required by the regulation. We were eager to see and open to consider alternate designs that would be effective, and perhaps even more attractive, in conveying the calorie information.

58. After the regulation was adopted, a guide for food service establishments on how to comply with the regulations was developed and mailed to all licensed establishments around March 1, 2007, well in advance of the effective date of the regulations (July 1, 2007). Attached hereto as Exhibit 12 is DOHMH brochure, “How to Comply: What your establishment needs to know about posting calories on menus and menus and menu boards.” The guide for compliance provided instructions for submitting alternative design proposals by email. The Department established an email account (calorielabeling@health.nyc.gov), which is checked at least daily for questions and submissions. Upon receipt of a submission, representatives from four Department programs review the proposal and judge its adherence to the alternative proposal

requirements. Establishments receive individualized responses in writing; average response time has been less than two weeks.

59. The Department gave preliminary approval for an alternative design proposal from Boston Market to provide calorie information for menu items on a calorie banner on their display cases. In the Boston Market restaurant environment, customers order primarily from display cases, so the design was deemed to meet criteria for prominence equal to what is otherwise required by Health Code §81.50(b)(1).

60. In addition, the Department informed the companies that the use of large stanchion designs for drive thrus at Dunkin' Donuts, McDonald's and Burger King locations would be approvable, because in this setting their prominence and likelihood of being seen by a customer in a unidirectional drive thru line was felt to meet the equal prominence test. The department also provided specific feedback to other FSEs that their designs only needed small modifications in order to be approved (for example, Auntie Anne's and Arby's). Subway, whose original poster alternative design was rejected, submitted a second proposal that was deemed to meet the standard requirements of the calorie labeling regulation and has now been implemented (see photo).

61. In replying to the generically-described alternate design schemes outlined by the National Restaurant Association in a February 13, 2007 letter to Deputy Commissioner Mary T. Bassett, the Department wrote that while most designs would not meet the prominence and point-of-decision standards, we would keep an open mind to stanchion signs as a potentially acceptable alternative. However, after the submission of some specific alternate design proposals, including one from Dunkin' Brands, and after multiple site visits to evaluate visibility of proposed alternatives and review of legibility standards, the Department's view was that the

in-store stanchion sign approaches as proposed would not meet the equal prominence standard. There were several reasons for this: (1) it is reasonable to assume that customers focus most of their attention on the menu board, rather than additional restaurant signage, in order to make their selections, (2) menu boards are usually easily visible from most or all pre-purchase areas of stores and even outside, in contrast to the proposed stanchions which are only visible from a small part of the store area and clearly do not meet the “equal prominence” standard of the Health Code, (3) stanchion signs could be moved, damaged or misplaced more easily than a menu board, and (4) customers who do not wait in line would not necessarily see the stanchion sign.

62. Although we considered and subsequently rejected the in-store stanchion sign approach, we continue to maintain an open mind to alternate designs.

63. Counter mat displays were deemed to not meet the prominence standard outlined in Health Code §81.50. These formats are not easily visible until a customer reaches the cash register, and even then only if the customer looks down; they are not permanent fixtures; they can easily be moved (e.g., during cleaning) or covered (e.g., by purses, trays or other personal items); and consulting counter displays while in line could be perceived to inconvenience other customers who are still waiting. Proposed posters were also not as easily visible from multiple points in the store and generally had smaller print than required.

64. I note that the declarations from Mr. Colon (McDonald’s) and Mr. Fitzgerald (Dunkin’ Donuts) describe menu boards as the most important real estate in food service establishments. This confirms the Department’s position that posting calories on menu boards is the most important and prominent venue to maximize effectiveness of the regulations in informing consumer purchase decisions.

65. Dunkin' Donuts submitted a sample menu board in an attempt to demonstrate that calorie information would not fit along with price information. From that sample, the Department's director of graphics produced a replica of the menu board with comparable fonts and layout to demonstrate that calories could be listed easily and visibly, as shown in the illustrations below, and in Mr. Krueger's declaration.. These modifications, as well as the earlier examples, provide clear evidence that calorie listings required by the regulations are feasible to implement with basic graphic design techniques.

	Calories	Sm	Calories	Md	Calories	Lg	Calories	X-lg
COFFEE	14	1.29	20	1.59	28	1.89	34	21.9
ICED	15	1.29	22	1.59	30	1.89		
Original • Decaf • Flavored								
TURBO HOT™	14	2.19	20	2.59	28	2.69	34	21.9
ICED	15	1.29	22	1.59	30	1.89		
Coffee with a shot of Espresso								
LATTE	116	2.19	186	2.59	232	2.69		
ICED	124	1.29	199	1.59	259	1.89		
Espresso & Milk								
Available in Caramel or Mocha Swirl								
LATTE LITE	14	2.19	20	2.59	28	2.69		
ICED	15	1.29	22	1.59	30	1.89		
ESPRESSO			4		one shot .99	extra shot .99		
CAPPUCINO	85	2.19	136	2.59	170	2.69		
BOX O' JOE®					140	9.99		
COFFEE BY THE POUND						6.99		

	Cal	Sm	Cal	Md	Cal	Lg	Cal	X-lg
COFFEE	14	1.29	20	1.59	28	1.89	34	21.9
ICED	15	1.29	22	1.59	30	1.89		
Original • Decaf • Flavored								
TURBO HOT™	14	2.19	20	2.59	28	2.69	34	21.9
ICED	15	1.29	22	1.59	30	1.89		
Coffee with a shot of Espresso								
LATTE	116	2.19	186	2.59	232	2.69		
ICED	124	1.29	199	1.59	259	1.89		
Espresso & Milk								
Available In Caramel or Mocha Swirl								
LATTE LITE	14	2.19	20	2.59	28	2.69		
ICED	15	1.29	22	1.59	30	1.89		
ESPRESSO			4		one shot .99	extra shot .99		
CAPPUCINO	85	2.19	136	2.59	170	2.69		
BOX O' JOE®							140	9.99
COFFEE BY THE POUND								6.99

Menu board sample supplied by Dunkin' Donuts (left) vs. DOHMH adaptation of Dunkin' Donuts sample menu board (right).

Customization is not a bar to calorie labeling.

66. Health Code §81.50 applies only to FSEs that have made calorie information publicly available, and only to those menu items with published information. Publication of calorie information for an item indicates that an establishment has an level of standardization that allows it to produce reliable calorie estimates. This is no different if the establishment provides

information on the internet, on a tray liner, or on a menu or menu board. Establishments can account for individual customization of an item by posting calories for the standard preparation of the item, along with a disclaimer that calorie amounts may differ due to individual preferences. Many establishments already provide such disclaimers on their publicly available calorie information. Alternatively, for certain products a range of calories can be provided.

Evaluation is essential to public health practice.

67. McDonald's DeMuth argues that the "scientific basis for this regulation is unsubstantiated." While the City disagrees with this statement given the published evidence that providing calorie information reduces calories chosen, and given that increased awareness of calorie content is in and of itself a valid governmental interest, enforcement of this regulation represents a unique opportunity to document that such an intervention can improve the health of the people of this City. As responsible public health practitioners we will assess the initiative through program evaluation. Program evaluation is an essential practice in public health and of the Department's programs, whether a program is newly established or longstanding. The importance of evaluation to program implementation is noted widely, and is considered by the US Centers for Disease Control and Prevention as part of the "10 Essential public health services" that should be undertaken in all communities.⁸⁶ The purpose of evaluation, the ninth of these activities, is to:

- Evaluate effectiveness, accessibility, and quality of personal and population-based health services.
- Provide information necessary for allocating resources and reshaping programs.

⁸⁶ Essential Public Health Services <http://www.cdc.gov/od/ocphp/nphpsp/EssentialPublicHealthServices.htm#es9> (accessed June 21, 2007)

The process of evaluation begins with the establishment of any program. Properly done, monitoring and evaluation offers systematic data that will guide program assessment improve program delivery and hold government accountable for health improvement, which is the ultimate goal of all public health action.⁸⁷

Summary

68. In summary, Health Code §81.50 is an important part of an integrated public response to a rapidly increasing epidemic of obesity and diabetes which has enormous human and financial costs to society. The restaurants covered by the regulation provide a large and apparently increasing proportion of food consumed by New Yorkers, and consumption of food in these establishments appears to increase risk of obesity and with it diabetes. Calories are by far the single most important piece of nutritional information, and the manner in which the regulated entities currently make this information available is both inaccessible and ineffective at providing this important information to consumers, who are unaware of and generally underestimate caloric content, with serious health consequences. There are consensus recommendations, broad evidence, and widespread social and scientific support for the rationale and soundness of this measure and for its likelihood of being effective in promoting more informed choice and healthier outcomes. The measure is a narrowly tailored minimum requirement that is feasible to implement and that creates a floor for communicating critical, and already public, calorie information, and does not in any way restrict communication of additional nutritional information.

⁸⁷ Centers for Disease Control and Prevention. Framework for program evaluation in public health. MMWR 1999;48(No. RR-11)

I declare under penalty of perjury pursuant to 28 U.S.C. §1746 that the foregoing is true and correct.

Executed on July 5, 2007



THOMAS R. FRIEDEN, M.D., M.P.H.